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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,941	04/30/2001	James F. Hemerick	6530.0278	8636

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EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/843,941

Applicant(s)
Hemerick et al.

Examiner
Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 10, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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Claims 14-18 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,306,294) in view of Lukic et al. (5,709,703). Winston et al. show elongated structure 12, stent accommodating area (just distal to flange 14) and engagement area (flange 14) which slides against the interior surface of the outer tubular structure since they are shown contacting one another in figures 1, 2 and 4. Winston et al. fail to show at least one marker band on the elongated structure. However, Lukic et al. teach that a marker band (33 or 41) should be placed on the inner elongated member of a stent delivery device proximate the stent accommodating area apparently in order to fluoroscopically determine the location of the stent within the body. Including such a marker band on the Winston et al. elongated structure 12 so that it too would have this advantage would have been obvious. As to claim 16, Winston et al. fail to show Pellethane as the material for the inner tubular structure. However, using Pellethane as the material for the inner tubular structure would have been obvious since it is well known as a desirable material for this use as indicated on page 2, lines 8-10 of applicant's specification. As to claims 17-18, note the plurality of external tubular structure contact areas 14 in figure 4 of Winston et al.

Claims 10-12, 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,306,294) in view of Mikus et al. (5,830,179). Winston et al. show the claimed device except

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for the distal end of the outer tubular structure 20 being translucent. However, Mikus et al. teach that the outer tubular structure 13 of a stent delivery device should be transparent in order to enable an endoscope to view markings 47, 48 used to measure the prostate gland (col. 8, lines 1-19). Making the outer tubular structure 20 of Winston et al. translucent so that it too would have this advantage would have been obvious.

Claims 1-4 and 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,306,294) in view of Lukic et al. (5,709,703) as applied to claims 14-18 and 24-28 above, and further in view of Mikus et al. (5,830,179) for the reasons set forth in the paragraph above. As to claim 34, lines 23-24, a marker band placed on the Winston et al. elongated structure 12 and viewed (fluoroscopically) as taught by Lukic et al. would be beneath the outer tubular structure which would be translucent as taught by Mikus et al. As to claim 35, retracting the Winston et al. stent back into the outer tubular structure and then repositioning the stent delivery system when it is determined that the stent is not initially properly positioned would have been obvious since it is well known in this art to so retract and reposition stents for this reason.

Claims 5-9,¹² 19-23, 29-33 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,306,294) in view of Burns (5,100,381). Winston et al. show the claimed

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device except for each subsequently proximal external structure 14 increasing in durometer. However, Burns teaches that the distal portion of a catheter should be more flexible than the proximal portion in order to allow the catheter to be advanced through the rather tortuous paths of the arteries while maintaining pushability (col. ²~~1~~, lines 30-34 and col. 3, line 65 to col. 4, line 6). Making the distal portion of the Winston et al. catheter 12 more flexible than the proximal portion so that it too would have this advantage would have been obvious. With this modification, the distal portion of the Winston et al. catheter 12 (which includes a distal flange 14) would be made of a material which is more flexible (with a low durometer) than a proximal portion of the catheter 12 (which includes a proximal flange 14) made of a high durometer, stiffer material.

Claims 13 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofmann et al. (5,810,837). Hofmann et al. show outer tubular structure 3, inner elongated structure 10, 9, 7, stent accommodating area 14, external tubular surface contact area (the outside surface of member 10) projecting from a surface (the outside surface of member 9) of the inner elongated structure and a gap between an external surface of the external tubular surface (the outside surface of member 10) and the internal surface 18 of the outer tubular structure 3 since the outer diameter C of member

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10 is 4.5 mm while the inner diameter B of outer tubular structure 3 is 4.6 mm (col. 4, line 38).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Note col. 10, lines 27-30 of Herweck et al. (6,475,244) and col. 7, lines 6-16 of Helgerson et al. (5,695,499).


Applicant's arguments with respect to claims 1-46 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
February 6, 2003


MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731